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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,321	09/16/2005	Tatsuo Horizoe	0425-1214PUS1	8222
2292 7590 08/22/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
SPIVACK, PHYLLIS G				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
08/22/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/549,321

**Applicant(s)**

HORIZOE, TATSUO

**Examiner**

Phyllis G. Spivack

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-20, 22 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 11-15, 18, 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 16, 17, 19, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Applicants' Amendment filed April 30, 2008 is acknowledged. Claims 4, 21 and 23-26 are canceled. Accordingly, claims 1-3, 5-20, 22 and 27-29 are pending.

The subject matter under consideration remains those agents for treating an inflammatory bowel disease comprising a combination of sulfasalazine and 5, 3-{3-[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid, claims 1-3, 5-10, 16, 17, 19, 20 and 22. The subject matter under consideration remains entirely drawn to **composition** claims. Claims 11-15, 18 and 27-29 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected subject matter.

Objections or rejections that are not herein reiterated are withdrawn. The following objections and rejection constitute the only objections and rejection applied to the present claims.

The disclosure is objected to for the following informality: The agent in claims 1-3, 5-10, 16, 17, 19, 20 and 22 represents a chemically, physically or biologically active principle or entity. In this case the agent is a discrete combination of two different compounds. Claim 22 appears to be directed to administration of compound a and compound b. The agent, however, is the mixed combination and separate administration cannot apply.

Appropriate correction is required.

Claims 4 and 19-22 were objected to in the last Office Action under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject

matter of a previous claim. It was asserted intended use (recited in claims 19 and 20) confers no patentable weight to composition claims.

Applicants traverse the objection and request further reasoning.

The subject matter of claim 22 is directed to the combination of compound (a) and(b). The separation of the two compounds, as in the distinct administration of one and then the other, does not find proper antecedent basis in claim 1, from which it depends.

The claimed agent is a finite entity with specific chemical and physical properties. Whether that agent is to be administered to treat ulcerative colitis (claim 19) or Crohn's disease (claim 20), no further limitation relating to the agent's properties is noted.

The objection of claims 19, 20 and 22 is maintained.

Claims 1-10, 16, 17 and 19-23 were rejected under 35 U.S.C. 103(a) in the last Office Action as being unpatentable over The Merck Manual, in view of Matsuura et al., US 2004/0102634. It was asserted The Merck Manual clearly teaches combination therapy for the treatment of inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis. The aminosalicylic acid derivative, sulfasalazine, is a part of recognized drug protocols for both bowel diseases. See, in particular, pages 306 and 310-311. Matsuura teaches the administration of the elected specie compound, 3-{[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid, specifically to treat ulcerative colitis and Crohn's disease. See Example 323, page 115, and page 189, claim 57.

Applicant argues the present invention has achieved unexpected results that rebut any asserted *prima facie* case of obviousness. Reference is made to the Example and Tables 1-5 in the instant specification wherein the combinations of 1) a PPAR $\gamma$  agonist compound - that is not the elected specie – and sulfasalazine, and, 2) the combination of the same PPAR $\gamma$  agonist compound and cyclosporine, show superior and unexpected medicinal effects.

The showing on page 47 of the specification is clearly not commensurate in scope with the subject matter under consideration, i.e., the combination of sulfasalazine and 5, 3-{3-[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid in a colitis model.

Thus in the absence of a showing of unexpected results **commensurate in scope** with the claims, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the aminosalicilic acid derivative, sulfasalazine, and 3-{3-[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid for the treatment of inflammatory bowel diseases.

In view of the combined teachings of The Merck Manual and Matsuura, the skilled artisan in formulation chemistry would have been motivated to prepare a combination agent comprising sulfasalazine and 3-{3-[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid to treat ulcerative colitis or Crohn's disease. The prior art (Merck) is very clear that it is beneficial to combine drugs in order to provide an efficacious treatment modality for patients suffering from inflammatory bowel diseases.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 14, 2008

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614